

10/576807

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DATE OF DEPOSIT	April 21, 2006	EXPRESS MAIL NO. EV321985034US
I HEREBY CERTIFY THAT THIS CORRESPONDENCE (ALONG WITH ANY PAPER REFERRED TO AS BEING ATTACHED OR ENCLOSED) IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL "POST OFFICE TO ADDRESSEE" BEFORE 5 P.M. ON THE ABOVE DATE IN AN ENVELOPE ADDRESSED TO COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.		
Name	Lori Schepisi	Signature
	Lori Schepisi	Date
		April 21, 2006

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Clark
Serial No.:	To Be Assigned - Case No.: 21487YP
Filed:	April 21, 2006
For:	METHOD FOR IDENTIFYING COMPOUNDS THAT AFFECT EXPRESSION OF TRYPTOPHAN HYDROXYLASE ISOFORM 2

Art Unit:

Examiner:

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR 1.97**

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98(a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith

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Case No.: 21487YP  
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5. In accordance with 37 CFR 1.97, (check one)

X the attached information is filed within three months of the filing date of the captioned case.

— the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.

— the attached information is filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

— the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.117(p).

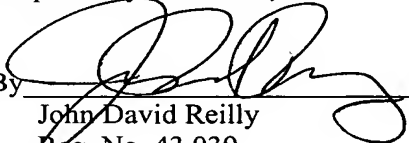
— each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

— each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart application and *this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.*

— no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

6. Statement under 37 C.F.R. §1.98(d). Copies of the references were submitted in prior application \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing dated under 35 U.S.C. §120.

Respectfully submitted,

By   
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Date: April 21, 2006

21487YP

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>AP12 COMPLETE IF KNOWN</b> 21 APR 2006		
			Application Number	To Be Assigned	
			Filing Date		
			First Named Inventor	Clark	
			Group Art Unit		
			Examiner Name		
Sheet	2	of	4	Attorney Docket Number	21487YP

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Azmitia, et al., "Corticosterone Regulation of Tryptophan Hydroxylase in Midbrain of the Rat", Science, Vol. 166, December 1969, pp. 1274-1476.
		Azmitia, et al., "Adrenalcortical Influence on Rat Brain Tryptophan Hydroxylase Activity", Brain Research, Vol. 78, 1974, pp. 291-302.
		Azmitia, et al., "Increase of Tryptophan Hydroxylase Enzyme Protein by Dexamethasone in Adrenalectomized Rat Midbrain", Journal of Neuroscience, Vol. 13, No. 12, December 1993, pp. 5041-5055.
		Balanoff, et al., "Cortisol Activity and Cognitive Changes in Psychotic Major Depression", American J. of Psychiatry, Vol. 158, No. 10, October 2001, pp. 1612-1616.
		Bethea, et al., "Steroid Regulation of Tryptophan Hydroxylase Protein in the Dorsal Raphe of Macaques", Biol. Psychiatry, Vol. 47, 2000, pp. 562-576.
		Blundell, "Serotonin and Appetite", Neuropharmacology, Vol. 23, No. 12B, 1984, pp. 1537-1551.
		Champier, et al., "Evidence for Tryptophan Hydroxylase and Hydroxy-Indol-O-Methyl-Transferase mRNAs In Human Blood Platelets", Life Sciences, Vol. 60, No. 24, 1997, pp. 2191-2197.
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		De Luca, et al., Analysis of the novel TPH2 gene in bipolar disorder and suicidality", Molecular Psychiatry, Vol. 9, 2004, pp. 896-899.
		GenBank Accession No. AY090565
		GenBank Accession No. J04758
		GenBank Accession No. NM 173353
		GenBank Accession No. NM 173391
		Gershon, et al., "The Enteric Nervous System", Ann Rev. Neurosci., Vol. 4, 1981, pp. 227-272.

Examiner Signature	Date Considered
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			Application Number Filing Date First Named Inventor Group Art Unit Examiner Name	To Be Assigned  Clark    
Sheet	3	of	4	Attorney Docket Number 21487YP

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Harvey, et al., "Support for the involvement of TPH2 gene in affective disorders", Molecular Psychiatry, Vol. 9, 2004, pp. 980-893.
		Jacobs, et al., "Structure and Function of the Brain Serotonin System", Physiological Reviews, Vol. 72, No. 1, January 1992, pp. 165-229.
		Kuhn, et al., "Determination of Some Molecular Parameters of Tryptophan Hydroxylase From Rat Midbrain and Murine Mast Cell", J. of Neurochemistry, Vol. 3, 1979, pp. 15-21.
		Kvetnansky, et al., "Stress and Molecular Biology of Neurotransmitter-Related Enzymes", Annals New York Academy of Sciences", pp. 342-356.
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		Park, et al., "Tryptophan hydroxylase activity in hypothalamus and brainstem of neonatal and adult rats treated with hydrocortisone or parachlorophenylalanine", Neuroscience Research, Vol. 7, 1989, pp. 76-80.
		Patel, et al., "Robust and Tissue-Specific Expression of TPH2 versus TPH1 in Rat Raphe and Pineal Gland", Biol. Psychiatry, Vol. 55, 204, pp. 428-433.
		Pecins-Thompson, et al., "Ovarian Steroid Regulation of Tryptophan Hydroxylase mRNA Expression in Rhesus Macaques", Journal of Neuroscience, Vol. 16, No. 21, November 1, 1996, pp. 7021-7029.
		Rastogi, et al., "Adrenocorticoids Control 5-hydroxytryptamine Metabolism in Rat Brain", Journal of Neural Transmission, Vol. 42, 1978, pp. 63-71.
		Seckl, et al., "Minireview: 11 $\beta$ -Hydroxysteroid Dehydrogenase Type 1 - A Tissue-Specific Amplifier of Glucocorticoid Action", Endocrinology, Vol. 142, No. 4, 2001, pp. 1371-1376.
		Singh, et al., "Increase in Cortical and Midbrain Tryptophan Hydroxylase Activity By Intracerebroventricular Administration of Corticotropin . . .", Neurochem. Int., Vol. 20, No. 1, 1992, pp. 81-92.

Examiner Signature	Date Considered
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**COMPLETE IF KNOWN**

## NON PATENT LITERATURE DOCUMENTS

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